PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Docket No: Q75927

Ryuichi MORISHITA, et al.

Continuation Application of

Appln. No.:09/660,522 Group Art Unit: 1636 (prior application)

Confirmation No.: Not yet assinged Examiner: David A. Lambertson (prior

application)

Filed: July 9, 2003

For: MEDICAMENT COMPRISING HGF GENE

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, along with a copy of the corresponding Communication from a Foreign Patent Office.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date for an application other than a continued prosecution application (CPA) under §1.53(d); (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a

INFORMATION DISCLOSURE STATEMENT

Continuation Application of U.S. Appln. No.: 09/660,522

request for continued examination (RCE) under §1.114, and therefore, no Statement under

37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such

document constitutes prior art against the claims of the present application. Applicant does not

waive any right to take any action that would be appropriate to antedate or otherwise remove any

listed document as a competent reference against the claims of the present application.

Respectfully submitted,

Registration No. 30,951

SUGHRUE MION, PLLC

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WASHINGTON OFFICE

PATENT TRADEMARK OFFICE

Date: July 9, 2003

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STATEMENT UNDER 37 C.F.R. § 1.97(e)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The undersigned hereby states, upon information and belief:

That each item of information contained in the Information Disclosure Statement filed concurrently herewith was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of said Information Disclosure Statement.

Respectfully submitted,

SUGHRUE MION, PLLC Susan J. Mack
Telephone: (202) 293-7060 Registration No. 30,951

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WASHINGTON OFFICE

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23373

PATENT TRADEMARK OFFICE Date: July 9, 2003

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q75927

Ryuichi MORISHITA, et al.

1.53(b) Continuation Appln. of Application No: 09/660,522

Confirmation No.: Not yet assigned

Group Art Unit: 1636 (prior application)

Filed: July 9, 2003 Examiner: D. Lambertson (prior application)

For: MEDICAMENT COMPRISING HGF GENE

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form which are all the references of record in parent applications No. 09/660,522 and 09/029,497. Applicant is not submitting duplicate copies of these references but requests that they be listed on the face of any patent granted on the above application. (See 37 CFR §1.98(d)). Copies of any cited copending applications, if not previously submitted, are being submitted herewith.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not

Information Disclosure Statement Continuation of U.S. Application No. 09/660,522

waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,

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Telephone: (202) 293-7060 Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373
PATENT TRADEMARK OFFICE

Date: July 9, 2003

Susan J. Mack

Registration No. 30,951

			Сотр	lete if Known	
Substitute for Form 1449 A & B/PTO			Application Number	Continuation Application of USSN 09/660,522)	
INFORMATION DISCLOSURE			Confirmation Number Not yet assigned		
STATEMENT	BY APPLIC	CANT	Filing Date	July 9, 2003	
			First Named Inventor	Ryuichi MORISHITA	
(use as many sh	eets as necessa	ry)	Art Unit	1636 (prior application)	
			Examiner Name	David A. Lambertson (prior application)	
Sheet 1	of	1	Attorney Docket Number	Q75926	

	U.S. PATENT DOCUMENTS								
Examiner	Cite	Document 1		Publication Date					
Initials*	No.1	Number	Kind Code ² (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document				
		US							
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	FOREIGN PATENT DOCUMENTS								
Examiner	Examiner Cite	Fo	reign Patent Docum	nent	Publication Date	Name of Patentee or			
Initials*	No.1	Country Code ³	Number ⁴	Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation ⁶		
		EP	0 461 560	A1	12/18/91	Toshikazu Nakamura	NA		
		WO	96/40062		12/19/96	Georgetown University	NA		
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	OTHER ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶					
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Examiner Signature	Date Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

				Complete if Known			
Substitute for Form 1449 A & B/PTO INFORMATION DISCLOSURE				Application Number	Continuation application of Appln. No. 09/660,522		
				Confirmation Number	Not yet assigned		
STAT	STATEMENT BY APPLICANT			Filing Date	July 9, 2003		
				First Named Inventor	Ryuichi MORISHITA		
(use	e as many she	ets as necessai	ry)	Art Unit	1636 (prior application)		
	•				D. Lambertson (prior		
				Examiner Name	application)		
Sheet	1	Of	2	Attorney Docket Number	Q75927		

	U.S. PATENT DOCUMENTS								
Evamina	Cito	Document N	Number	Publication					
Examiner Cite No.1 Number		Kind Code ² (if known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document					
		US							
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Examiner Cite	Cite	For	eign Patent Docum	nent	Publication Date	Name of Patentee or	
Initials*		MM-DD-YYYY	Applicant of Cited Document	Translation ⁶			
			 				
				 			

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.					
		December 30, 2002 Office Action issued in corresponding Taiwanese patent application.	No				
	-	ML LIU, et al., "Hepatocyte growth factor inhibits cell proliferation in vivo of rat hepatocellular carcinomas induced by diethylnitrosamine," Carcinogenesis, April 1995, 16(4): 841-3.	Abstract				
		Y. MATSUDA, et al., "Hepatocyte growth factor suppresses the onset of liver cirrhosis and abrogates lethal hepatic dysfunction in rats," J. Biochem., September 1995, 118(3): 643-9.	Abstract				
		G. SHIOTA, et al., "Inhibitory effect of hepatocyte growth factor on metastasis of hepatocellular carcinoma in transgenic mice," Res Commun Mol Pathol Pharmacol, January 1996, 91(1): 33-9.	Abstract				
		G. SHIOTA, et al., "Characterization of double transgenic mice expressing hepatocye growth factor and transforming growth factor alpha," Res Commun Mol Pathol Pharmacol, October 1995, 90(1): 17-24.	Abstract				
		G. SHIOTA, et al., "Hepatocyte growth factor in transgenic mice: effects on hepatocyte growth, liver regeneration and gene expression," Hepatology, April 1994, 19(4): 962-72.					
		G. SHIOTA, et al., "Hepatocyte growth factor inhibits growth of hepatocellular carcinoma cells," Proc Natl Acad Sci USA, January 1992, 89(1): 373-7.	Yes				

Examiner Signature	 Date Considered	<u></u>

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¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to indicate here if English language Translation is attached.

Form PTO-1449 (Rev. 2-32)

U.S. Department f Commerce Patent & Trademark Office

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)

Attorney Docket No:

Q75927

Continuation application of Appln. No. 09/660,522

Applicant: Ryuichi MORISHITA, et al.

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Group: 1636 (prior application)

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Examiner Initial	Document Number	Date Date	Name	Class	Sub- Class	Filing Date (if appropriate)
		 				
		 				
						
					 	
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		FOREIGN PAT	TENT DOCUMENTS			<u> </u>
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	OTHER DOCUM	ENTS (Including	g Author, Title, Date,	Pertinent Pag	es. Etc.)	
	Eliot M. Rosen et al.,					ion and angiogensis"
	Exs, Vol. 65, 1993, pr	. 301-310				
	Eliot M. Rosen et al.,				tent Angiog	enesis Factor In Vivo
	Symp. Society of Experience S. Grant et al.	erimental Biology	v, Vol. 47, 1993, pp. 2	27-234	oliva Duna A	Seel Annal Sei Wall
	March 1993, pp. 1937	., Scatter factor 7-1941	mouces blood vessel	(ottization in i	vivo, Froc. I	au. Acaa. Sci., Vol.
	Toshiaki Takebayash		yte Growth Factor/Sc	atter Factor M	fodulates Ce	ll Motility, Proliferat
	and Proteoglycan Syr 1411-1419	nthesis of Chond	rocytes", The Journal	of Cell Biolog	gy, Vol. 129	, No. 5, June 1995, p
	Naruya Tomita et al.,				", Biochemic	cal and Biophysical
EVALUATION:	Research Communic	ations, Vol. 186,	No. 1, July 1992, pp.		<u> </u>	
EXAMINER:	1 ASSECTE COMMUNICA	unons, 401. 100,	DATE CONSIDE			

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Group: 1636 (prior application)

		U.S. PATEN	T DOCUMENTS		` <u> </u>	11 /			
Examiner Initial	Document Number	Date	Name	Class	Sub- Class	Filing Date (if appropriate			
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			<u> </u>						
			ng Author, Title, Date, Henatocyte Growth F			Tissues". Biochen			
	and Biophysical Res	Nakamura et al., "Expression of Local Hepatocyte Growth Factor System in Vascular Tissues", Biocher and Biophysical Research Communications, Vol. 215, No. 2, 1995, pp. 483-488 Hayashi et al., "Autocrine-paracrine effects of overexpression of hepatocyte growth factor gene on growendothelial cells", Biochemical and Biophysical Research Communications, Vol. 220, No. 3, 1996, pp. 545							
	endothelial cells", Bi								
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EXAMINER:	<u> </u>		DATE CONSIDE	n PD					

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		U.S. PATE	ENT DOCUMENTS		7	1111
Examiner Initial	Document Number	Date	Name	. Class	Sub- Class	Filing Date (if appropriate)
	USPN 5,652,225	7/29/97	Isner et al.			
	USPN 5,756,122	5/26/98	Thierry et al			
		FOREIGN P.	ATENT DOCUMENTS	3		
	Document	Date	Country	Class	Sub- class	Translation Yes/No
	WO 96 40062A	12/19/96	WIPO			
	WO 91 06309A	5/16/91	WIPO		1	
	EP 0461 560A	12/18/91	EPO		-	
	EP 0494369	7/15/92	EPO			
	EP 0492614	7/1/92	EPO		1	
	WO 93/08821	5/13/93	WIPO			
	WO 94/06456	3/31/94	WIPO			
	WO 92/05184	4/2/92	WIPO			
						<u> </u>
	Nakamura et al., "MO FACTOR", Nature, V Miyazawa K. et al., "I HEPATOCYTE GRO	LECULAR C ol. 342, Nover MOLECULAR WTH FACTO	ling Author, Title, Date, LONING AND EXPRE inber 23, 1989, pages 44 CLONING AND SEQ DR" Biochetmical and Bi	SSION OF H 10-443, XP000 UENCE ANA	UMAN HEP. 0652120 ALYSIS OF c	DNA FOR HUMA
	T. Seki et al., "ISOLA GROWTH FACTOR Communications Vol	TION AND E FROM HUM 172, No. 1, O	67-973, XP000651424 EXPRESSION OF cDN AN LEUKOCYTE" Bio ctober 15, 1990, pages and the state of	ochemical and 321-327, XP0	Biophysical 02084490	
	l		cial News Paper (Decer			anguage translation
	<u> </u>		999 w/ English language			
	<u> </u>	·	Abstract No. 3459 (Oc	tober 21, 1997	")	
	Ueki et al., Nature M Research report from English language tra	the Welfare N	230, 1999 Ministry Specific Diseas	es, Pervaded	Lung Discase	es Sub-group (1997
	Ueda, et al., Ann. Th		·			
	Preprint farticle by	Taniyama et	al., entitled "Therapeuti	c Angiogenes	is Induced by	Human Hepatocyt

	(continued from the last page) Growth Factor Gene in Rat and Rabbit Hind Limb Ischemia Models: Pre- clinical Study to Treat Peripheral Arterial Disease."				
	Preprint of article by Aoki, et al., entitled "Angiogenesis Induced by Hepatocyte Growth Factor in Non-infarcted Myocardium and Infarcted Myocardium: Up-regulation of Essential Transcription Factor for Angiogenesis, Ets."				
	"Scatter Factor (Hepatocyte Growth Factor) is a Potent Angiogenesis Factor IN Vitro" by Rosen et al., Society of Experimental Biology, 1993, pp 227-234				
	"Scatter Factor Induces Blood Vessel Formation IN VIVO" by Grant, et al., Proc. Nat'l. Acad. Sci USA, Vol. 90, March 1993, pp 1937-1941				
	"Hepatocyte Growth Factor/Scatter Factor Modulates Cell Motility, Proliferation, and Proteoglycan Synthesis of Chondrocytes" by Takebayashi et al., Journal of Cell Biology, Vol. 29, No. 5 1995, pp 1411-1419				
	"The Interaction of HGF-SF with other Cytokines in Tumor Invasion and Angiogenesis" by Rosen et al., Vol. 65, 1993, pp. 301-310				
	Circulation 96, No. 8, October 21, 1997, No. 3459				
	Nature Medicine 5:226-230 (February, 1999)				
	Nature 338:557-562, 1989				
	Science 235:442-447, 1987				
	J. Clin. Invest. 93:662-670, 1993				
	J. Vasc. Surg. 16:181-191, 1998				
	Circulation 97:645-650, 1998				
	Circulation 98:2800-2804, 1998				
	J. Bone & Joint Surg. 71:74-80, 1989				
	New England J. Medicine 331:889-895, 1994				
	Gut, Supplement No. 5, Vol. 35, s-60, F240 (1994)				
	Biochem and Biophys Res. Comm. 220, 539-545 (1996), Hayashi et al., "Autocrine-paracrine effects of overexpression of hepatocyte growth factor gene on growth of endothelial cells				
	Verma et al., "Gene therapy promises, problems and prospects," Nature 389:239-242 (1997)				
	Morishita, et al., "Novel in vitro gene transfer method for study of local modulators in vascular smooth musc cells," Hypertension 21:894-899 (1993)				
					
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